



# European Commission Initiative on Breast Cancer:

*Concept Document*

2017

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JRC105454

EUR 28738 EN

PDF	ISBN 978-92-79-72125-0	ISSN 1831-9424	doi:10.2760/78078
Print	ISBN 978-92-79-72126-7	ISSN 1018-5593	doi:10.2760/169957

Luxembourg: Publications Office of the European Union, 2017

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How to cite: *European Commission Initiative on Breast Cancer: Concept document*; EUR 28738 EN; doi:10.2760/78078.



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# What is the European Commission Initiative on Breast Cancer?

The European Commission Initiative on Breast Cancer (ECIBC)<sup>1</sup> is an initiative led by the European Commission that aims to ensure and harmonise the quality of breast cancer services across European countries on a sustainable basis.<sup>2</sup>

1. <http://ecibc.jrc.ec.europa.eu>.

2. The ECIBC's impact is foreseen to spread beyond the EU as it is expected to be implemented in the 28 EU Member States, EU candidate countries (Albania, Iceland, Montenegro, The former Yugoslav Republic of Macedonia, Serbia and Turkey), EU potential candidates (Bosnia and Herzegovina and Kosovo), and EFTA members (Iceland, Liechtenstein, Norway and Switzerland).

## Rationale: why is ECIBC necessary?

### Breast cancer, the most commonly diagnosed cancer in Europe

According to WHO 2012 estimates, each year 2.6 million new cases of cancer are diagnosed in Europe (excluding non-melanoma skin cancers).<sup>3</sup> Breast cancer is the most frequent one with 364 000 new cases per year.

Each year in Europe, one woman out of 275 receives a diagnosis of breast cancer, making it by far the most frequently diagnosed cancer among women (28.8% of all newly diagnosed cancers).

### Breast cancer, the leading cause of death from cancer in women in Europe

Not only breast cancer is the most frequently diagnosed but, with 91 000 deaths each year in Europe, is also the first cause of death from cancer for women and the third in the overall population.

### Health inequalities in Europe related to breast cancer

There are substantial differences in breast cancer incidence, prevalence, mortality and survival in Europe.<sup>3,4,5,6</sup> For example in 2012, the estimated age-standardised mortality rate (number of women out of 100 000 dying of breast cancer) ranged from 15 to 29 (almost the double!) across countries of EU-27. Although the higher

3. Ferlay *et al.* (2013). Cancer incidence and mortality patterns in Europe: Estimates for 40 countries in 2012. *European Journal of Cancer*, 49(6):1374-1403 (<http://www.sciencedirect.com/science/article/pii/S0959804913000075>). WHO estimations for the EU-27 in 2012 are presented, as they are the most recent aggregated estimations which best apply to the geographical area covered by the ECIBC.

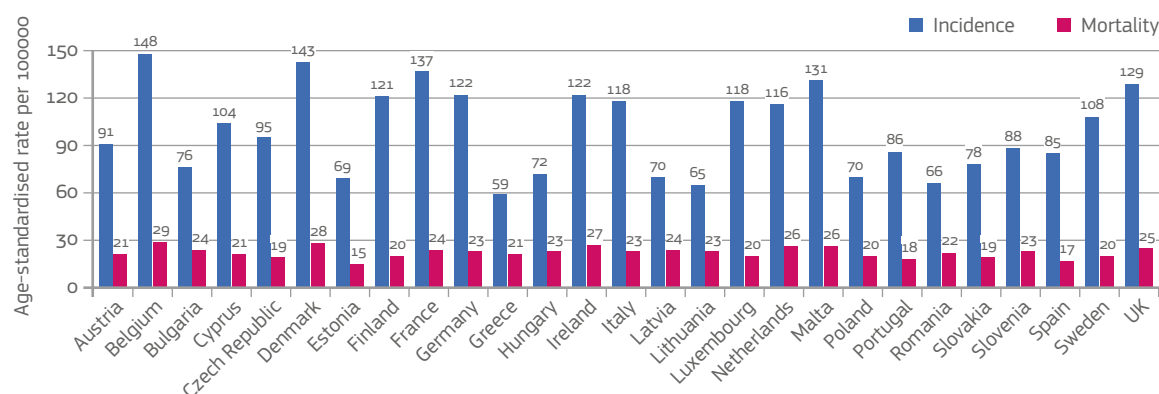
4. Allemani *et al.* (2010). Variation in 'standard care' for breast cancer across Europe: A EURO-CARE-3 high resolution study. *European Journal of Cancer*, 46(9):1528-1536 (<http://www.sciencedirect.com/science/article/pii/S095980491000119X>).

5. De Angelis *et al.* (2014). Cancer survival in Europe 1999-2007 by country and age: results of EURO-CARE-5—a population-based study. *The Lancet Oncology*, 15(1):23-343 (<http://www.sciencedirect.com/science/article/pii/S1470204513705461>).

6. Council Conclusions on reducing the burden of cancer. Luxembourg, 10 June 2008 ([http://www.eu2008.si/en/News\\_and\\_Documents/Council\\_Conclusions/June/0609\\_EPSCO-cancer.pdf](http://www.eu2008.si/en/News_and_Documents/Council_Conclusions/June/0609_EPSCO-cancer.pdf)).



mortality rates may reflect the higher incidence of breast cancer in some countries, in others they might be due to the lower survival of women with breast cancer, hence to health inequalities among countries.



**Figure 1.** Age-standardised incidence and mortality rates in Europe 2012: breast cancer (adopted from Ferlay et al., 2013).

These inequalities may be caused by several factors, such as differences in epidemiology of other fatal diseases, genetics, socio-economic status, exposure to risk factors, health policies (*e.g.* presence/absence of screening programmes), or the effective delivery of cancer control measures, among these, appropriate breast cancer care services.

### Differences in the quality of breast cancer services in Europe

Differences in the quality of healthcare services have been reported across European countries. Moreover, more than ten different quality assurance schemes of breast cancer services coexist in Europe:<sup>7</sup> to harmonise and improve the quality of care in breast cancer services in Europe a common set of benchmarking quality requirements is needed.

7. Report of a European survey on the organisation of breast cancer care services (<https://ec.europa.eu/jrc/en/publication/eur-scientific-and-technical-research-reports/report-european-survey-organisation-breast-cancer-care-services-supporting-information>).

In summary, there is room for tackling inequalities in cancer in Europe by addressing healthcare.<sup>8</sup> Therefore, a coordinated action at European level is needed to ensure that all European citizens have access to cancer care services with an essential level of quality and safety.

8. Commission communication on action against cancer 2009 ([http://ec.europa.eu/health/ph\\_information/dissemination/diseases/docs/com\\_2009\\_291.en.pdf](http://ec.europa.eu/health/ph_information/dissemination/diseases/docs/com_2009_291.en.pdf)).

## What is the legal ground for the ECIBC?

While it is up to national governments to organise healthcare and ensure that it is provided, the EU does not define health policies, nor the organisation and provision of health services and medical care.

The EU's role is to support national policies by

- helping EU governments achieve shared objectives;
- generating economies of scale by pooling resources;
- helping EU countries tackle shared challenges – pandemics, chronic diseases or the impact of increased life expectancy on healthcare systems.<sup>9</sup>

With this spirit, in December 2003, the Council adopted the *Council Recommendation on cancer screening*,<sup>10</sup> which recommended population-based screening programmes for breast, cervical and colorectal cancers in accordance with European guidelines. The adoption of European guidelines on best practice was identified as key for ensuring the development of high quality cancer-screening programmes. Therefore, the European Commission coordinated the development of screening guidelines: for breast cancer the latest was the 4<sup>th</sup> edition of the *European Guidelines for Quality Assurance in Breast Cancer Screening and Diagnosis*,<sup>11</sup> including best practices defined by consensus of experts.

In 2007 the Lisbon Treaty was signed (*Consolidated Treaty of the EU*)<sup>12</sup> and included specific provisions on the health policy. According to Title XIV, Article 168, the Commission may promote cooperative actions particularly ‘to combat the major cross-border health scourge and take initiatives aiming at the establishment of

9. [https://europa.eu/european-union/topics/health\\_en](https://europa.eu/european-union/topics/health_en).

10. <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2003:327:0034:0038:EN:PDF>.

11. <https://publications.europa.eu/en/publication-detail/-/publication/7945b8d-fa10-4e88-a781-9a7c36cf3411>.

12. <http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=OJ:C:2016:202:TOC>.

**guidelines and indicators**, the organisation of **exchange of best practice**, and the preparation of the necessary elements for **periodic monitoring and evaluation** and adopt incentive measures’.

In 2008, both the *European Parliament Resolution*<sup>13</sup> and the *Council Conclusions on reducing the burden of cancer*<sup>14</sup> called on the Commission ‘to support the development of **European accreditation/certification programmes** in cancer screening, diagnosis and treatment based on European quality-assurance guidelines’. They further called on ‘to explore the potential for the development of voluntary European accreditation schemes for cancer screening and appropriate follow-up of lesions detected by screening, such as a European pilot accreditation scheme for breast cancer screening and follow-up based on the European guidelines for quality assurance in breast cancer screening and diagnosis’.

Other acts are also relevant to the framework of ECIBC:

- The *Council Recommendation on Patient Safety*:<sup>15</sup> the minimum requirements set by the Recommendation will have to be included in the ECIBC.
- The *Directive on the application of patients’ rights in cross-border healthcare*:<sup>16</sup> relevant both for patients’ safety aspects and for patients’ rights to transparent information on performance of healthcare services across borders.
- The *Regulation for Accreditation and Market Surveillance*<sup>17</sup> and its implementation acts provide the legal basis for ensuring an officially recognised peer reviewing system for the ‘European accreditation/certification programmes’ developed upon the Council Conclusions.

13. <http://www.europarl.europa.eu/sides/getDoc.do?pubRef=-//EP//TEXT+TA+P6-TA-2008-0121+0+DOC+XML+Vo//EN>.

14. [http://www.eu2008.si/en/News\\_and\\_Documents/Council\\_Conclusions/June/0609\\_EPSCO-cancer.pdf](http://www.eu2008.si/en/News_and_Documents/Council_Conclusions/June/0609_EPSCO-cancer.pdf).

15. [http://ec.europa.eu/health/sites/health/files/patient\\_safety/docs/council\\_2009\\_en.pdf](http://ec.europa.eu/health/sites/health/files/patient_safety/docs/council_2009_en.pdf).

16. <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2011:088:0045:0065;EN:PDF>.

17. <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2008:218:0030:0047;en:PDF>.

# What are the general goal and specific objectives?

## General goal

Within the Commission's actions on chronic diseases, ECIBC's overall goal is to contribute to improve health and to reduce health inequalities in Europe by ensuring and improving the quality of breast cancer services.

## Specific objectives

In order to contribute to the overall goal, ECIBC aims to achieve the following specific objectives:

*Objective 1:* To propose evidence-based recommendations on screening and care for breast cancer services in Europe

The ECIBC considers six processes along the breast cancer care pathway:

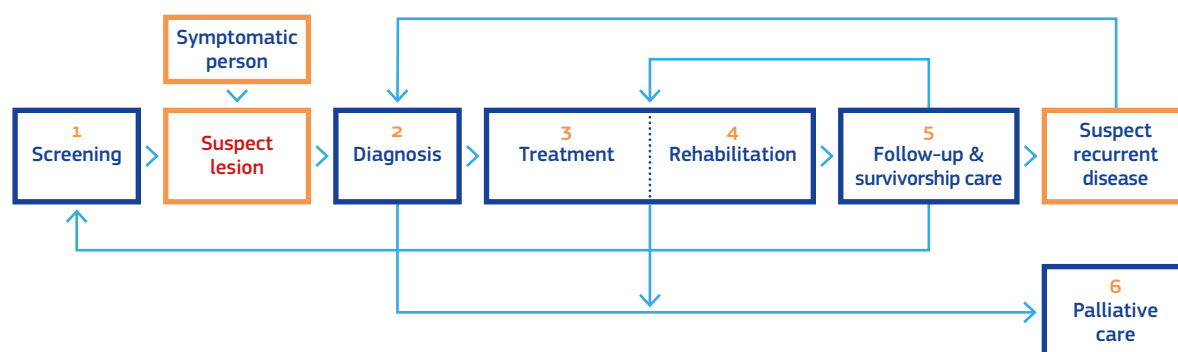


Figure 2. General breast cancer care pathway.

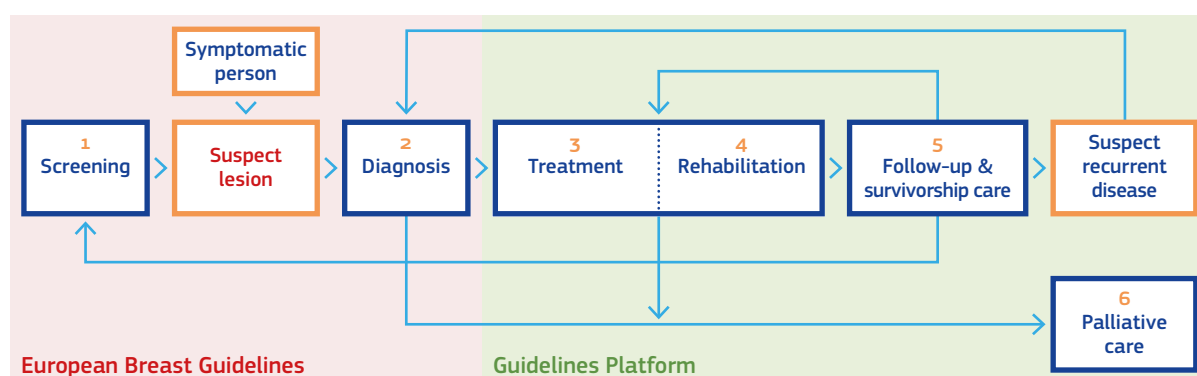
*Objective 1.1:* To develop the European Guidelines for Breast Cancer Screening and Diagnosis (the *European Breast Guidelines*) based on new knowledge and evidence

Coordinated by the JRC, the *European Breast Guidelines* start from the work of the 4<sup>th</sup> edition of the *European Guidelines for Quality Assurance in Breast Cancer Screen-*

ing and Diagnosis (published in 2006).<sup>11</sup> In line with 2008 Council conclusions, the *European Breast Guidelines* provide evidence-based recommendations for the screening and diagnostic processes of breast cancer services. They are developed with GRADE<sup>18</sup> and have a web-based format.

**Objective 1.2:** To create a platform of guidelines for breast cancer treatment, rehabilitation and follow-up

For the other processes of the breast cancer pathway than screening and diagnosis (see *Figure 2*), as well as all relevant horizontal aspects, JRC develops a web-based platform of evidence-based guidelines (*Guidelines Platform*). This platform, together with the *European Breast Guidelines*, provides the evidence on which the requirements of the *European QA scheme* are built.



**Figure 3.** Breast cancer care processes covered by the European Breast Guidelines and the Guidelines Platform.

The guidelines to be evaluated for inclusion in the *Platform* are identified by a systematic search and a call to stakeholders for including also non-publicly available guidelines. The *Guidelines Platform* includes guidelines on breast cancer fulfilling AGREEII<sup>19</sup> criteria, plus the presence of a structural updating plan and of an identified contact person.

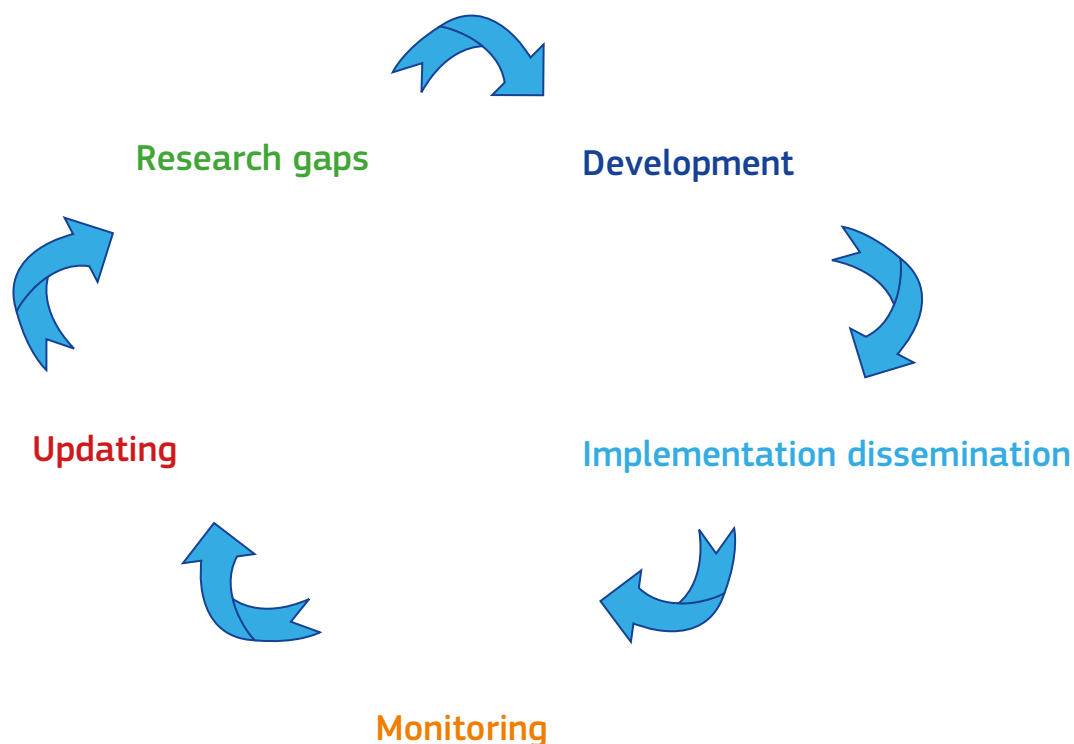
18. <http://www.gradeworkinggroup.org>.

19. <http://www.agreetrust.org/agree-ii/>.

Beyond their use for the *European QA scheme*, the *Guidelines Platform* is intended to be a valuable resource available to the public but in particular to professionals, policy makers, researchers, and guidelines developers. The ultimate impact of the *Guidelines Platform* will be to contribute to the reduction of unnecessary variability in breast cancer services and hence contribute to improve the outcomes of breast cancer patients in terms of morbidity, mortality, and quality of life.

**Objective 1.3:** To propose a procedure to maintain the evidence-based recommendations for breast cancer services up-to-date in the long term

The JRC will define a methodology to assess the need for updating the *European Breast Guidelines* and to incorporate in them all breast cancer care processes. It will apply this approach to warrant that the *European Breast Guidelines* and the recommendations collected in the *Guidelines Platform* are based on the best available and up-to-date evidence.



**Figure 4.** *Guidelines (and overall ECIBC) lifecycle.*

*Objective 2: To develop a voluntary European QA scheme for Breast Cancer Services based on the EU legislative framework on accreditation, as defined in the Regulation of the European Parliament and of the Council setting out the requirements for accreditation and market surveillance*

The *European QA scheme* focus on requirements that are relevant to people. Certification/accreditation along the *European QA scheme* will be voluntary. The scheme respects the autonomy of European countries while steering towards the harmonisation and coordination of existing quality standards and of new ones where evidence should support them. The *European QA scheme* is synergic with already existing schemes in the countries while proposing a roadmap towards continuous improvement.

The *European QA scheme* includes a set of quality and safety requirements for breast cancer services in Europe. The factors considered to select the requirements/indicators to be implemented are:

- quality potential, as derived by the pathway,
- relevance as derived from the most updated evidence-based guidelines (the *European Breast Guidelines* and the *Guidelines Platform*),
- relevant legislation,
- professional best practices,
- available data collections,
- organisational settings, and
- feedback from countries related to implementation needs.

The scheme is based on the European legal framework for accreditation,<sup>17</sup> hence under harmonised peer supervision across all involved countries under the co-ordination of the European co-operation for Accreditation (EA);<sup>20</sup> hence is potentially usable by all countries associated to EA. The *European QA scheme* covers all

20. <http://www.european-accreditation.org>.



the healthcare processes of breast cancer care as reported in *Figure 3*. Before being made available to users, the scheme is tested for its robustness across a limited but significant number of services resuming the diversity of situations and settings.

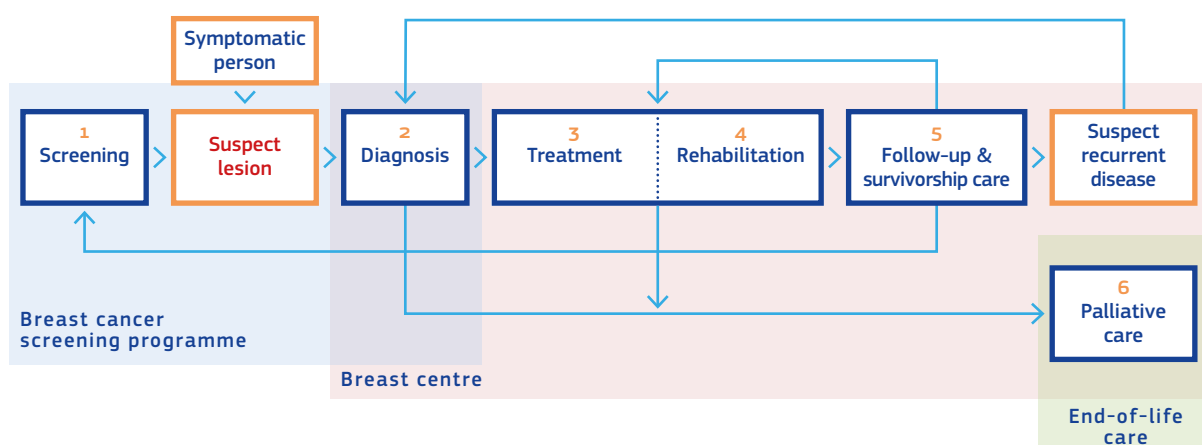
In order to respect the variability of breast cancer care organisation across countries, the *European QA scheme* has a modular structure. A module is a distinct process or aggregation of processes (*e.g.* screening and diagnosis) which falls under the responsibility of a single entity. As not always breast care is provided by one single entity, but by several which are administratively independent from each other, the *European QA scheme* allows for modular certification. The following breast cancer care modules may ask for certification:

- **Screening** (organised, population-based) – corresponding to the process screening, including or not including the process ‘diagnosis’ after positive screening events.
- **Breast centre** – corresponding to the processes: diagnosis, treatment, follow-up, rehabilitation and survivorship care, and palliative care.
- **End-of-life care** – corresponding to the process ‘palliative care’.

Three different scenarios for this modular approach in certification are foreseen:

- **One module approach:** one legal entity is responsible for the whole pathway, from screening to end-of-life care. No processes are outsourced.
- **Two modules approach:** one legal entity is responsible for screening (*e.g.* regional authority) and another one is responsible for all (for all processes from treatment to end-of-life care (*e.g.* hospital). No processes are outsourced.
- **Three modules approach:** one legal entity is responsible for screening (*e.g.* regional authority), another one is responsible for all processes from treatment to follow-up (*e.g.* hospital), and a third one covers end-of-life care (*e.g.* local home care service, or hospice).

For each approach, a comprehensive (*i.e.* ‘single site’) or network (*e.g.* multisite cancer centre) feature will be available in order to guarantee the maximum level of flexibility and adaptation to local characteristics. A schematic presentation of the three modules approach is given in *Figure 5*.



**Figure 5.** Modular approach with three modules for the European QA scheme.

**Objective 3:** To develop a European template for training on digital breast screening

A template for training on digital breast screening is to be developed. It is directed towards two main profiles involved in screening programmes: radiologists and radiographers. The template is developed by (i) deriving it from existing templates and (ii) considering the countries' legal frameworks for professionals licencing and competence.

To design an implementable training template that is respecting countries' legal frameworks, the ECIBC carried out two parallel actions:

1. Carried out a thorough search for existing templates.
2. Launched a survey for receiving information on the content of the existing trainings and on the legislations in place.

It is meant to be a requirement for competence and training for professionals providing digital breast screening in the services adhering to the *European QA scheme*. It is being developed in coordination with countries and experts and the modalities for its deployment are being defined (e.g. *e-learning* platform + hands-on training).

If successful, the same methodology may be applied for developing training templates for other professional profiles covered by the *European QA scheme*.

**Objective 4:** To develop a long-term web hub hosting all the deliverables

The ECIBC web hub<sup>21</sup> is the communication interface of the initiative towards all stakeholders. It is the gateway to retrieve the most updated information about the outputs and tools produced within ECIBC. Its development is coordinated by JRC which stays tuned with the stakeholders' inputs.

For instance, a woman wishing to know whether she should attend breast cancer screening should be able to find on the ECIBC web hub a recommendation, the corresponding quality requirements for the service providing screening under the *European QA scheme*, and the list of screening services, with respective performance levels, that obtained the certification in the area of interest for her.

The web hub is user-friendly, adapted to the needs of persons as well as health professionals. Moreover the web hub provides a platform for collaboration and exchange for those stakeholders that are directly involved in ECIBC, such as the working groups developing the *European Breast Guidelines* and the *European QA scheme*. Moreover, the web hub may serve as an example for other initiatives tackling other cancer types and health problems. More details can be found in the ECIBC web hub concept and feasibility study.<sup>21</sup>

21. [http://ecibc.jrc.ec.europa.eu/documents/20181/22500/ECIBC+web+hub+concept+and+feasibility+study\\_Report.pdf](http://ecibc.jrc.ec.europa.eu/documents/20181/22500/ECIBC+web+hub+concept+and+feasibility+study_Report.pdf).

## The FUTURE: Expected benefits

### 1. Greater confidence in breast cancer services

Citizens will receive clear information on what to expect when seeking care at breast cancer services certified by the *European QA scheme*. This can increase the confidence in the quality of breast cancer services in Europe.

Provision of clear and comprehensive information on the quality of breast cancer services is in line with the implementation of the directive on patients' rights in cross-border healthcare (DIRECTIVE 2011/24/EU). The certification of breast cancer centres across countries by the *European QA scheme* will allow for comparing breast cancer care within and across country borders and thus help patients to make an informed decision on where to seek treatment.

### 2. Reduction of health inequalities in Europe

By improving the quality of breast cancer services in Europe, the ECIBC aims at contributing to reduce the burden of cancer and at decreasing the avoidable differences in breast cancer incidence, prevalence, mortality and survival.

### 3. Effective implementation and updating of the evidence

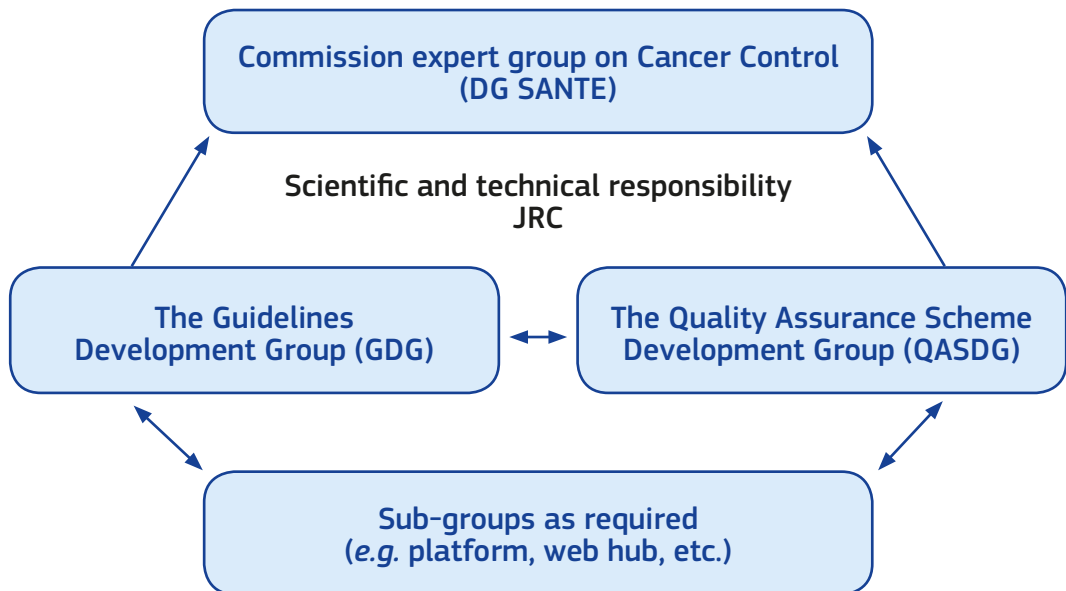
The ECIBC model uses the *European QA scheme* to ensure, via its requirements, that evidence based recommendations provided by guidelines are implemented. This may reduce unnecessary variability in healthcare provision and outcomes. In addition, the continuous feedback from auditees and auditors within the *European QA scheme* is expected to foster the updating of the guidelines.

### 4. Model transferrable to other health problems

The ECIBC model is being developed as a 'blueprint' for other health problems. Given its modular nature, in case of success, the ECIBC model would be easily

transferred to other cancers or other diseases and healthcare areas, with the possibility to develop one or more of its parts (the *Guidelines*, the *QA scheme* or both). In addition, the modules used to simplify the care models applied in Europe, can be considered also for other care pathways. Its extension to colorectal and cervical cancers is something to be considered.

## ECIBC structure



**Figure 6.** Policy responsibility and endorsement of European Breast Guidelines and European QA scheme.<sup>22</sup>

### 1. The Coordination Role

The European Commission coordinates ECIBC. In particular the Directorate-General Health and Food Safety (**DG SANTE**) owns the policy leadership in health-related topics, in particular the EU public health policy on cancer,<sup>23</sup> while the Joint Research Centre (**JRC**), thanks to an agreement with DG SANTE, coordinates the Initiative ensuring consistency, synchronisation and rigorous methodology for all its parts.

<sup>22</sup>. As described in the DG SANTE governance document ([http://ec.europa.eu/health/sites/health/files/major\\_chronic\\_diseases/docs/eibc\\_structure\\_2014\\_en.pdf](http://ec.europa.eu/health/sites/health/files/major_chronic_diseases/docs/eibc_structure_2014_en.pdf)).

<sup>23</sup>. [http://ec.europa.eu/health/major\\_chronic\\_diseases/diseases/cancer\\_en](http://ec.europa.eu/health/major_chronic_diseases/diseases/cancer_en).

The Commission is the most appropriate Institution to coordinate this initiative as:

- it has the means to steer the initiative in the long-term, granting ECIBC's **sustainability**,
- it provides a neutral platform for bringing together a wide range of actors and stakeholders at EU level, thus granting ECIBC **neutrality**,
- it possesses the tools for granting transparency, such as taking into account stakeholders' inputs, through calls for feedback.

Several Commission services are involved in ECIBC pooling their resources and expertise to develop and implement this unique initiative that can change the face of breast cancer healthcare. Also other cancer-related activities (*e.g.* the Commission expert group on Cancer Control<sup>24</sup> and the Joint Action CanCon) are informed and required to contribute. The Commission expert group on Cancer Control is a forum for Member States and stakeholders to provide input into cancer policies at EU level. They review the ECIBC in order to guarantee its full compatibility and coordination with the overall EU policies on cancer.<sup>25</sup>

## 2. The Technical Role

### 2.1. Technical coordination

JRC coordinates the scientific, technical, organisational and administrative aspects of the work. JRC also provides the outsourced supports, the collaborating tools and logistics for the ECIBC working groups and other involved stakeholders. JRC also ensures appropriate communication with other EC services and relevant working/expert groups and projects.

24. <http://ec.europa.eu/transparency/regexpert/index.cfm?do=groupDetail.groupDetail&groupID=3203&NewSearch=1&NewSearch=1>.

25. The Commission expert group on Cancer Control, created by Commission decision of 3 June 2014 and repealing Decision 96/469/EC ([http://ec.europa.eu/health/sites/health/files/major\\_chronic\\_diseases/docs/com2014\\_c167\\_05\\_en.pdf](http://ec.europa.eu/health/sites/health/files/major_chronic_diseases/docs/com2014_c167_05_en.pdf)), assists DG SANTE in its policy responsibility in the cancer domain in the drawing up of legal instruments and policy documents, guidelines and recommendations on cancer control at the request of the Commission.

## 2.2. The working groups

For the first two objectives of the initiative, two working groups, the ‘**Guidelines Development Group**’ (GDG) and the ‘**Quality Assurance Scheme Development Group**’ (QASDG), were created in Autumn 2015 following a call for expression of interest organised by DG SANTE. The selection process followed the rules for establishing scientific and consultative groups in the European Union. The *European Breast Guidelines* and the *European QA scheme* will be developed with the support of the GDG and QASDG, respectively.

More working groups may be set up on demand to support or accomplish the remainder objectives of the initiative, e.g. the *Guidelines Platform*.

## 2.3. The outsourced technical teams

The JRC, in view of both sustainability and neutrality, outsources any necessary services according to the usual tendering procedures of the Commission.

In this line, an **outsourced systematic review team**, the Iberoamerican Cochrane Centre (CCIb),<sup>26</sup> is supporting the GDG in performing systematic reviews and developing evidence-based recommendations; they are also contracted for evaluating the guidelines to be hosted in the *Guidelines Platform*. Moreover, the European co-operation for Accreditation (EA)<sup>20</sup> has been contracted for providing support to the QASDG both in the development and in the piloting phase of the *European QA scheme* (and to ensure that all National Accreditation Bodies will be ready to run it once approved). IQ Healthcare,<sup>27</sup> on the other hand, is supporting the QASDG in the methodology aspects of the definition of requirements and indicators.

Representatives of the outsourced technical teams are attending the relevant meetings. In case of need of additional expertise, scientific advisors or external experts are appointed to provide their inputs in the meetings.

26. <http://es.cochrane.org/home>.

27. <http://www.iqhealthcare.nl/en/>.



Observers (apart from Commission officials) cannot participate in the working group meetings. Observers may, however, join the ECIBC Plenaries, where relevant achievements of both working groups are summarised and relevant scientific topics are discussed.

## 2.4. Input of Member States, other European Countries and stakeholders

Member States, EFTA, candidate and interested countries, and other relevant stakeholders are invited to express their opinion and suggestions on activities performed by the different working groups at various development stages of ECIBC. For instance they provide feedback on the scope of the guidelines and of the *QA scheme*, can submit documents (*e.g.* guidelines), etc.

### 2.4.1. The group of ECIBC National Contacts

The JRC has asked the 28 EU Member States plus other European Countries to nominate a National Contact as a focal point to represent each participating Country during the projects course. Delegates are required to provide their contribution at various development stages of ECIBC. The continuous communication with the National Contacts is essential for ensuring that the ECIBC respects the countries' perspectives and own healthcare and quality assurance set-ups throughout the project thus providing the basis for the successful implementation of the European QA scheme.

### 2.4.2. Other stakeholders

Other relevant parties or individuals involved by ECIBC (experts, patient's organisations, professional societies, industry, etc.) are invited to participate, for instance via the Calls for feedback organised for the key outputs of the Initiative.

## 3. External Peer-Review

JRC arranges peer review from external experts for the publication of the key deliverables of the project, for example, for the final version of the *European Breast Guidelines*.

## Working methods

### Person-centred approach

ECIBC promotes an approach that considers the needs, preferences and values of people using or being possible users of breast cancer services. For the work of ECIBC this implies that persons and patient advocates are actively involved in all stages of the development of ECIBC outputs (*e.g.* being members of GDG and QASDG).

### Inclusive and multidisciplinary approach

JRC is making a great effort to foster networking<sup>28</sup> to involve in ECIBC all the profiles: Individuals from the key areas for the project are involved in the working groups, views of interested parties (entities and individuals) are being integrated via Calls for feedback, contributing in this way to ECIBC's successful implementation hence to increase its impact.

Based on this cooperative approach, ECIBC brings together a wide range of actors at a European level, including healthcare users, experts, professionals, NGOs, patient groups, civil society representatives, the industry, policy makers and involved countries' representatives (ECIBC National Contacts).

### Evidence-based methods

ECIBC applies rigorous methods based on the best available evidence. The requirements of the *European QA scheme* will be based on recommendations that will rigorously consider their evidence base. The recommendations provided by the *European Breast Guidelines* will be developed according to rigorous methods (*e.g.* GRADE<sup>18</sup> when applicable), and therefore will be based on the systematic review of the evidence.

28. *European Commission Initiative on Breast Cancer–ECIBC: Organisation of project guiding and support meetings: Meetings 2011-2013* (<https://ec.europa.eu/jrc/en/publication/eur-scientific-and-technical-research-reports/european-commission-initiative-breast-cancer-ecibc-organisation-project-guiding-and-support>).

## Transparent and explicit working modalities

The ECIBC working modalities promote transparency in different ways:

1. It follows the rules implemented by the Commission to enhance transparency for its experts groups. All profiles, declarations of interest and photos of GDG and QASDG members, list of the ECIBC National Contacts, the minutes of GDG and QASDG working groups meetings are published online in the web hub.
2. The state-of-art of ECIBC is continuously updated on the web hub. The deliverables are being submitted to Calls for feedback and peer reviewing. The final outputs will be publicly available on the web hub and disseminated through publications.
3. The GRADE<sup>18</sup> approach is being followed to develop the healthcare recommendations. It is a transparent and explicit approach to grading the quality of evidence and strength of recommendations in healthcare. Other explicit and transparent methods will be applied when GRADE<sup>18</sup> is not appropriate.
4. The requirements for the *European QA scheme* will be developed following a modified The RAND/UCLA Appropriateness Method.<sup>29</sup> This implies that, in a structured and transparent consensus process, requirements will be selected for their relevance considering their evidence base and their feasibility to be implemented in all European countries. This consensus involves experts from all relevant fields of breast cancer care and patients and National Contacts (for the implementability aspects).
5. Outsourcing of services functional to the objectives are always being organised via public tenders following the most transparent rules for contracting services. This outsourcing part is important both for ensuring a competent, independent and timely support to the ECIBC working groups.

## Independent approach

The scientific advice is independent of all commercial, private and national interests, and is derived from the scientific assessment of topics evaluated.

29. [https://www.rand.org/content/dam/rand/pubs/monograph\\_reports/2011/MR1269.pdf](https://www.rand.org/content/dam/rand/pubs/monograph_reports/2011/MR1269.pdf).

The ECIBC follows the European Commission rules on management of Conflict of Interest: the members of the working groups and other contributors are asked to act in their own personal capacity and this implies a careful balance between the scientific and objective expertise and the possible other interests both of financial and intellectual nature. To grant independence, the JRC not only collects and publishes the annual declarations and collects the specific-to-meeting-declarations but, most important, evaluates and manages potential conflicting interests, *e.g.* by proposing abstentions from voting and decisions and including a summary of abstentions in the minutes of each meeting (made available on the ECIBC web hub).

### **Monitoring of progress**

Annual reports are being submitted to DG SANTE and made publicly available. All actions, outputs, events related to the ECIBC are constantly made available to the public via the ECIBC web hub.

## Life-cycle plan

The ECIBC framework model provides an optimised and potentially standardised way of:

- translating from recommendations (guidelines) to requirements (QA scheme),
- navigating across different care processes along the whole care pathway,
- reducing duplication of effort and resources, and
- transparently involving stakeholders.

In addition, a long-term monitoring strategy of ECIBC impact is planned to be developed. It will include a set of processes and outcome indicators that will be defined by experts in this field, along with a description of data that need to be collected for estimation of each indicator. The respective indicators will be monitored at breast cancer service or at population-based level and will be compared with an evidence-based desired level of performance (where applicable) or with a baseline value. The examples from best practice in this area will be followed, considering also the availability of data in different countries.

## Budget and timeline

The Commission allocates a budget of 4 000 000 EUR to the JRC for activities on cancer, which include ECIBC. The JRC jointly contributes by providing a sustainable infrastructure and a dedicated team<sup>30</sup> in charge of the development and implementation of ECIBC. For more detail: *Commission Implementing Decision 2011/C 358/06*.<sup>31</sup>

The first set of recommendations of the *European Breast Guidelines* were made available on the ECIBC web hub in 2016 and a new set is added in 2017.

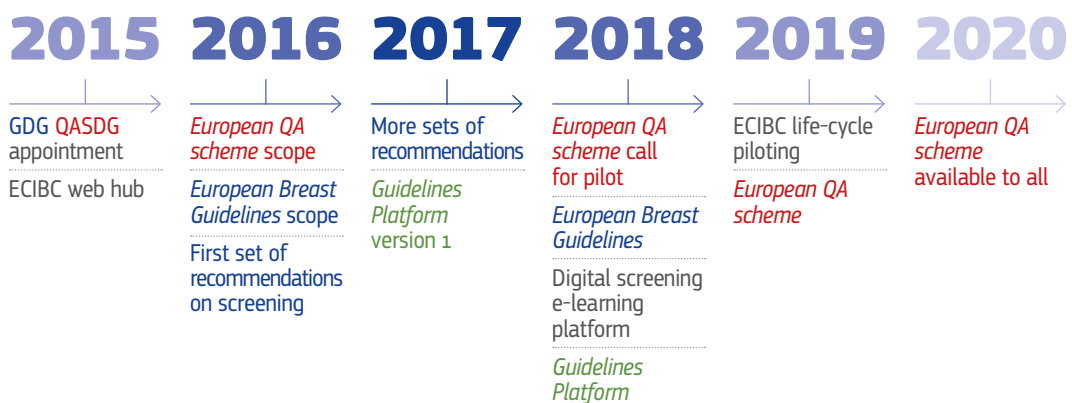


Figure 7. ECIBC timeline.

30. <http://ecibc.jrc.ec.europa.eu/ecibc-team>.

31. [http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32011D1208\(01\)&from=EN](http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32011D1208(01)&from=EN).

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